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Board of Governors of the Federal Reserve System, December 3, 1986.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 86-27571 Filed 12-8-86; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Additions to Senior Executive Service Performance Review Board Membership

Title 5, U.S.C. 4314(c)(4), of the Civil Service Reform Act of 1978, Public Law 95-454, requires that the appointment of Performance Review Board members be published in the *Federal Register*.

On October 2, 1986, the Department of Health and Human Services' PRB membership was published in the *Federal Register*. The following members are hereby added to that membership:

Thomas R. Burke

Dennis J. Fischer

Dated: December 2, 1986.

Thomas S. McFee,

Assistant Secretary for Personnel Administration.

[FR Doc. 86-27603 Filed 12-8-86; 8:45 am]

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Food and Drug Administration

[Docket No. 86E-0460]

Determination of Regulatory Review Period for Purposes of Patent Extension; Duromedics Cardiac Valve Prosthesis

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for the Duromedics Cardiac Valve Prosthesis and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESS: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Health Affairs

(HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) generally provides that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under that act, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension, that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 158(g)(3)(B).

FDA recently approved for marketing the Duromedics Cardiac Valve Prosthesis, which is indicated for use as a replacement for diseased, damaged, or malfunctioning natural or prosthetic aortic or mitral heart valves. Based on this approval, Hemex, Inc., now seeks patent term restoration.

FDA has determined that the applicable regulatory review period for the Duromedics Cardiac Valve Prosthesis is 864 days. Of this time, 651 days occurred during the testing phase of the regulatory review period, while 213 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun:* April 19, 1984. FDA has verified the applicant's claim that a clinical investigation for the product was begun on April 19, 1984.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act:* January 29, 1986. The applicant claims the premarket approval application

(P850006) was initially submitted on February 4, 1985. However, the application did not contain sufficient information to permit substantive review by FDA until receipt of an amendment on January 29, 1986.

3. *The date the application was approved:* August 29, 1986. FDA has verified the applicant's claim that P850006 was approved on August 29, 1986.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, the applicant requests an extension until August 29, 2000.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 9, 1987, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before June 7, 1987, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 96th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 3, 1986.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 86-27551 Filed 12-8-86; 8:45 am]

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Public Health Service

Health Resources and Services Administration; Statement of Organization, Functions and Delegations of Authority

Part H, Chapter HB (Health Resources and Services Administration) of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (47 FR 38409-24, August 31, 1982, as amended most recently at 51 FR